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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,076	10/03/2001	John A.T. Young	960296.97745	9060

7590 12/03/2003

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EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	19

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/970,076	Applicant(s) YOUNG ET AL.	
	Examiner N. M. Minnifield	Art Unit 1645	

-- Th MAILING DATE of this communication appears on th cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7,11-13 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7,11-13 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☒ Interview Summary (PTO-413) Paper No(s). 11/13/03
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed July 28, 2003 is acknowledged and has been entered. Claims 8-10 have been canceled. Claims 5 7 and 19 have been amended. Claims 5-6, 11-13 and 19-21 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment and/or comments with the exception of those discussed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. It is noted that Applicants are entitled to the filing date of 10/3/01, not the filing date of the provisional application 60/251481 filed 12/5/00. The provisional application is not in compliance with the CRF Rules. If Applicants desire priority back to the provisional application, Applicants should direct the Examiner to the exact support, by page and sequence number, in the specification of the provisional application. Further, the provisional application is not available to the Examiner at present.

Applicants have stated (July 28, 2003 amendment) that the sequences disclosed in the pending application were not disclosed in the provisional application. Therefore, the effective filing date for the pending nonprovisional application is October 3, 2001.

4. Claims 5-7, 11-13, and 19-21 are rejected under 35 U.S.C. 102(a) as being anticipated by WO200134626-A1 (Accession #:AAD5303), Accession # BC012074 from NCBI.

The prior art discloses a polynucleotide sequence that has 99.7% similarity/identity with the claimed SEQ ID NO: 1. The prior art discloses the claimed polynucleotide sequence of SEQ ID NO: 1 or a fragment thereof. The prior art discloses methods for producing the polypeptide encoded by the polynucleotide sequence.

Applicants have asserted that neither sequence anticipates the claims as amended, a polynucleotide that encodes a soluble polypeptide. Applicant's arguments filed January 13, 2003 have been fully considered but they are not persuasive. The sequences (accession numbers) disclose both the nucleotide sequences (SEQ ID NO:1) and amino acid sequences (SEQ ID NO:2). With regard to the polypeptide being soluble, it would appear that this is an inherent property since the same sequences are disclosed.

The claimed invention is anticipated by the prior art. The prior art anticipates the claimed invention by disclosing the polynucleotide having the same or similar characteristics as claimed. The polynucleotide in the prior art is believed to inherently possess properties which anticipates the claimed invention or if they are not the same the polynucleotide, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the polynucleotide of the prior art is evidenced to meet the limitations of the claimed polynucleotide, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' polynucleotide with the polynucleotide of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the polynucleotide of the prior art does not possess the same material structural and functional characteristics of the claimed polynucleotide) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection is maintained for the reasons of record. Applicant's arguments filed July 28, 2003 have been fully considered but they are not persuasive. Applicants have asserted that the Examiner has overlooked that the polynucleotide sequence cited against the claims is not a soluble peptide, but rather encodes a polypeptide having a transmembrane region, which corresponds to the 23 amino acid long putative transmembrane region of SEQ ID NO:2. Applicants have asserted that the specification states that the soluble fragments that maintain a PA-binding activity are of great interest as these can competitively inhibit anthrax toxin binding to the anthrax toxin receptor. Such fragments are not disclosed in the cited art, and the cited art provides no teaching or suggestion to select or employ the claimed portions of the full-length polynucleotide or polypeptide sequences. Further, Applicants have asserted that this distinction is a prima facie difference in structure, that this structural difference forms a basis for a functional distinction by Applicants' invention over the cited prior art. However, the claims do not recite the functional distinction that Applicants have asserted that the specification states at paragraph [00035]. The claims do not recite that the polypeptide competitively binds up anthrax toxin and prevents binding to the native (cell-bound) anthrax

toxin receptor. Further, it is noted that claim 1(b) of the prior art (WO 2001/34656) claims a polypeptide fragment, see also claims 2-4. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art discloses the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Further, the recitation of "consisting essentially of" is open and closed claim language, therefore the prior art would appear to anticipate the claimed invention.

5. The rejection of claims 5-9, 11-13 and 19-21 under 35 U.S.C. § 102(a) as anticipated by Bradley et al 2001 (Nature, 414(6860):225-229) is withdrawn. It is noted that the Bradley et al article indicates/states that this issue of the journal *Nature* was issued on November 8, 2001, after the effective filing date of the pending application.

6. Claims 5-7 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by St. Croix et al (2000).

The prior art discloses the polynucleotide sequence as set forth in claimed SEQ ID NO: 1 or a fragment thereof (see accession # AF279145).

Applicants have asserted that neither sequence anticipates the claims as amended, a polynucleotide that encodes a soluble polypeptide. Applicant's arguments filed January 13, 2003 have been fully considered but they are not persuasive. The sequences (accession numbers) disclose both the nucleotide

sequences (SEQ ID NO:1) and amino acid sequences (SEQ ID NO:2). With regard to the polypeptide being soluble, it would appear that this is an inherent property since the same sequences are disclosed.

The claimed invention is anticipated by the prior art. The prior art anticipates the claimed invention by disclosing the polynucleotide having the same or similar characteristics as claimed. The polynucleotide in the prior art is believed to inherently possess properties which anticipates the claimed invention or if they are not the same the polynucleotide, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the polynucleotide of the prior art is evidenced to meet the limitations of the claimed polynucleotide, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' polynucleotide with the polynucleotide of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the polynucleotide of the prior art does not possess the same material structural and functional characteristics of the claimed polynucleotide) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection is maintained for the reasons of record. Applicant's arguments filed July 28, 2003 have been fully considered but they are not persuasive. Applicants have asserted that the Examiner has overlooked that the polynucleotide sequence cited against the claims is not a soluble peptide, but rather encodes a polypeptide having a transmembrane region, which corresponds to the 23 amino

acid long putative transmembrane region of SEQ ID NO:2. Applicants have asserted that the specification states that the soluble fragments that maintain a PA-binding activity are of great interest as these can competitively inhibit anthrax toxin binding to the anthrax toxin receptor. Such fragments are not disclosed in the cited art, and the cited art provides no teaching or suggestion to select or employ the claimed portions of the full-length polynucleotide or polypeptide sequences. Further, Applicants have asserted that this distinction is a prima facie difference in structure, that this structural difference forms a basis for a functional distinction by Applicants' invention over the cited prior art. However, the claims do not recite the functional distinction that Applicants have asserted that the specification states at paragraph [00035]. The claims do not recite that the polypeptide competitively bind up anthrax toxin and prevent binding to the native (cell-bound) anthrax toxin receptor. Further, it is noted that claim 1(b) of the prior art (WO 2001/34656) claims a polypeptide fragment, see also claims 2-4. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art discloses the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Further, the recitation of "consisting essentially of" is open and closed claim language, therefore the prior art would appear to anticipate the claimed invention.

7. No claims are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
November 3, 2003